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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,807	02/24/2004	Mark Gelfand	LE-218J	1195

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/784,807	Applicant(s) GELFAND ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) 12-16, 19, 35-44, 53-57, 60 and 67-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 17, 18, 20, 45-52, 58, 59 and 61-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5-15-06;3-16-06;12-2-05;9-6-05;6-29-05.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in the reply filed on 1-16-07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The reply filed 1-16-07 failed to address an election of species. In a telephonic conversation with John Shanske on 1-29-07 election was made to pursue the species B (figure 2). In that conversation claims 1-11,17-34,41-52,58-66 were stated as reading on the elected species.
3. Claims 12-16,19,35-44,53-57,60,67-97 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1-16-07 and telephonic conversation of 1-29-07. Note claims 19,41-44, and 60 were stated as reading on the elected species but after further review they are deemed non-readable.

Claim Objections

4. Claim 23 is objected to because of the following informalities: in line 5, " a particularly" should be replaced with --at particular--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "hypotensive surgery" is not understood as the specification fail to define hypotensive surgery.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the subject matter of claims 62 and 63 are not described in the specification.

8.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-3,8-10,17,18,20,45-47,49-51,58,59,61,64,65 are rejected under 35 U.S.C. 102(b) as being anticipated by Guiset US PN 4044401.

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11. Guiset et al. disclose in figure 1 and corresponding description a method of protecting a kidney or inhibiting a natural function of a kidney during surgery comprising artificially increasing pressure (by mere placement of balloon 27 or inflation by reservoir 23) which reduces or inhibits natural renal function and thereafter reducing pressure.

Note the method disclose may be utilized in a natural bladder rather than artificial rigid bladder 6.

12. Claims 1-3,5,6,8-11,17,18,20,45-47,49-52,58,59,61,63-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Cioanta et al. US PN 6682555.

13. Cioanta et al. disclose a method of protecting a kidney or inhibiting a natural function of a kidney during surgery comprising artificially increasing pressure (by inflation of balloon 15 or 52, see figure 10B) which reduces or inhibits natural renal function and thereafter reducing pressure. Column 14, line 41 through column 15 line 28 disclose various contrast agents which may be delivered after pressure within the urinary tract is increased.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 4,48,62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guiset US PN 4044401.

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16. Guiset disclose the limitations of claims 4,48, and 62 as described above but lack the express written disclosure of increasing the pressure to about 15 cmH20.

However, Guiset disclose pressure created by pressing on reservoir 23 causing fluid 24 to inflate balloon 27 thereby increasing pressure inside the bladder in order to open the collar 16 and release urine. The pressure created must be sufficient to overcome a normally closed collar 16. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Guiset to provide a required pressure of at least about 15 cmH20 to open the collar in order to ensure the collar remain closed when urination is not required.

17. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cioanta et al. US PN 6682555 in view of Donald Induced hypotension and blood loss during surgery.

18. Cioanta et al. disclose the limitations of claim 7 as described above but lack the express written disclosure of the surgery comprising a hypotensive surgery. As best understood, hypotensive surgery implies surgery wherein blood pressure is somehow reduced. Cioanta disclose a surgery but fail to disclose blood pressure is reduced.

Donald teach general anaesthetics used during surgery typically cause a decrease in blood pressure and potentially reduce blood loss. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Cioanta by providing a general anaesthetic during surgery causing a decrease in blood pressure and reduction of potential blood loss.

Allowable Subject Matter

19. Claims 21-34 are allowed. Note claim 23 requires a grammatical correction as described above.

20. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to disclose or substantially render obvious a method of preventing or treating contrast nephropathy inpatients undergoing radiographic procedures comprising the steps of increasing pressure in a urinary tract, injecting contrast agent into a blood vessel, and reducing pressure in the urinary tract.

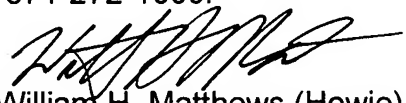
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Matthews (Howie)
Examiner
Art Unit 3738